

Decision Memo for Tumor Antigen by Immunoassay CA 19-9 (Modification of Code List to Include ICD-9-CM Code 156.2, Malignant neoplasm of Ampulla of Vater) (CAG-00275N)

Decision Summary

CMS has determined that ICD-9-CM diagnosis codes 156.0, Malignant neoplasm of the gallbladder and 156.2, Malignant neoplasm of the Ampulla of Vater, flow from the existing narrative for conditions for which tumor antigen by immunoassay CA 19-9 is reasonable and necessary. We intend to modify the list of "ICD-9-CM Codes Covered by Medicare" in the NCD for tumor antigen by immunoassay CA 19-9 to include these codes.

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Decision Memo

This coding analysis does not constitute a national coverage determination (NCD). It states the intent of the Centers for Medicare & Medicaid Services (CMS) to issue a change to the list of ICD-9-CM Codes Covered that are linked to one of the negotiated laboratory NCDs. This decision will be announced in an upcoming recurring update notification in accordance with CMS Pub 100-4, Chapter 16, section 120.2 and will become effective as of the date listed in the transmittal that announces the revision.

To: Administrative File: CAG-00275N Tumor Antigen by Immunoassay CA 19-9 (Modification of Code List to Include ICD-9-CM Code 156.2, Malignant Neoplasm of Ampulla of Vater)

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RE: Coding Analyses for Tumor Antigen by Immunoassay CA 19-9

Date: March 11, 2005

I. Decision

CMS has determined that ICD-9-CM diagnosis codes 156.0, Malignant neoplasm of the gallbladder and 156.2, Malignant neoplasm of the Ampulla of Vater, flow from the existing narrative for conditions for which tumor antigen by immunoassay CA 19-9 is reasonable and necessary. We intend to modify the list of "ICD-9-CM Codes Covered by Medicare" in the NCD for tumor antigen by immunoassay CA 19-9 to include these codes.

II. Background

On December 22, 2004, CMS began a coding analysis for expansion of the ICD-9-CM covered codes list for the tumor antigen by immunoassay CA 19-9 NCD. Immunoassay determinations of the serum levels of certain proteins or carbohydrates serve as tumor markers. When elevated, serum concentration of these markers may reflect tumor size and grade. CA 19-9 levels are useful in monitoring the response of certain malignancies to therapy and assessing whether residual tumor exists post-surgical therapy.

III. History of Medicare Coverage

In accordance with section 4554 of the Balanced Budget Act of 1997, CMS entered into negotiations with the laboratory community regarding coverage and administrative policies for clinical diagnostic laboratory services. As part of these negotiations, we promulgated a rule that included 23 NCDs. These NCDs included the tumor antigen by immunoassay CA 19-9. The rule was proposed in the March 10, 2000 edition of the Federal Register (65 FR 13082) and was made final on November 23, 2001 (66 FR 58788). The final rule called for a 12-month delay in effectuating the NCDs in accordance with the recommendations of the negotiating committee. Thus, the NCDs became effective on November 25, 2002.

In the laboratory NCDs, CMS determined that specific tests were reasonable and necessary for certain medical indications. These decisions were evidence-based, relying on scientific literature reviewed by the negotiating committee. The NCDs contain a narrative describing the indications for which the test is reasonable and necessary. We also developed a list of ICD-9-CM codes that designate diagnoses/conditions that fit within the narrative description of indications that support the medical necessity of the test. This list is entitled "ICD-9-CM Codes Covered by Medicare," and includes codes where there is a presumption of medical necessity.

In addition, we developed two other ICD-9-CM code lists. The second list is entitled "ICD-9-CM Codes Denied," and lists diagnosis codes that are never covered by Medicare. The third list is entitled "ICD-9-CM Codes that do not Support Medical Necessity," and includes codes that generally are not considered to support a decision that the test is reasonable and necessary, but for which there are limited exceptions. Tests in this third category may be covered when they are accompanied by additional documentation that supports a determination of reasonable and necessary. We determined in the tumor antigen by immunoassay CA 19-9 NCD that any ICD-9-CM code not listed in either of the ICD-9-CM covered or not covered sections would be categorized into this group that does not support medical necessity.

IV. Timeline of Recent Activities

On December 22, 2004, CMS open a coding analysis item regarding tumor antigen by immunoassay CA 19-9 after receiving a request from Debbie Beedlow of Hematology and Oncology Consultants in Orlando, Florida. Ms Beedlow's request was limited to inclusion of ICD-9-CM code 156.2, Malignant neoplasm of the Ampulla of Vater. However, in reviewing the request, we believed that a similar argument could be made for ICD-9-CM code 156.0, Malignant neoplasm of gallbladder. We posted a tracking sheet to the Internet site (<http://cms.hhs.gov/mcd/viewtrackingsheet.asp?id=146>), soliciting public comment for 30 days on the appropriateness of adding codes 156.0 and 156.2 to the list of covered diagnoses for tumor antigen by immunoassay CA 19-9.

At the end of the public comment period, January 21, 2005, we had received three comments. All three of the comments expressed support for the proposed addition of ICD-9-CM codes 156.0 and 156.2 to the list of covered diagnoses for CA 19-9.

V. General Methodological Principles

During the negotiation meetings that led to the development of the 23 clinical diagnostic laboratory NCDs, we stated our intent that the narrative of the NCDs reflect the substance of the determinations. The addition of the coding lists was intended as a convenience to the laboratories and as a means of ensuring consistency among the Medicare claims processing contractors as they interpreted the narrative conditions that support coverage. Thus, all of the codes in the covered code list must flow from the narrative indications of the NCD. We reiterated this position in the November 23, 2001 final rule (66 FR 58795) and in subsequent implementing instructions (Program Memorandum AB-02-110).

VI. CMS Analysis

As noted above, we have taken the position that the "ICD-9-CM Codes Covered by Medicare" list is intended to contain only those codes that flow from the narrative of the indication in the NCD. The tumor antigen immunoassay CA 19-9 NCD lists the following as an indication for testing:

The tumor antigen by immunoassay CA 19-9 NCD includes the following indication:

"Levels are useful in following the course of patients with established diagnosis of pancreatic and biliary ductal carcinoma."

We believe that the ICD-9-CM codes 156.0, Malignant neoplasm of gallbladder, and 156.2, Malignant neoplasm of Ampulla of Vater, flow from the existing narrative indications statement quoted above. We believe that both gallbladder and Ampulla of Vater malignancies are appropriately considered as biliary duct cancer. Consequently, we intend to issue a recurring update to the edit module implementing the NCDs to add ICD-9-CM codes 156.0 and 156.2 to the list of the ICD-9-CM codes covered for tumor antigen by immunoassay CA 19-9.

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